Stephanie McCutcheon

v.

Enlivant ES, LLC, d/b/a Seasons Place Assisted Living Facility

EXHIBIT A

Case Docket Entries

CC-13-2021-C-48

Court: **Circuit** County: **13 - Greenbrier** Created Date: **6/3/2021** Security Level: **Public**

Judge: **Jennifer P. Dent** Case Type: **Civil** Case Sub-Type: **Other** Status: **Open**

Related Cases:

Style: **Stephanie McCutcheon v. Enlivant ES, LLC, a foreign limited liability company, d/b/a Seasons Place Assisted Living Facility**

	Entered Date	Event	Ref. Code	Description
1	6/3/2021 3:14:53 PM	E-Filed		Complaint
	1-1 6/3/2021	Civil Case Information Statement		
	1-2 6/3/2021	Complaint - Complaint		
	1-3 6/3/2021	Supporting Document - Exhibits A-E		
	1-4 6/3/2021	Transmittal		
	1-5 6/3/2021	Summons		
2	6/3/2021 3:14:53 PM	Judge Assigned	J-13001	Jennifer P. Dent
3	6/3/2021 3:14:53 PM	Party Added	P-001	Stephanie McCutcheon
4	6/3/2021 3:14:53 PM	Party Added	D-001	Corporate Creations Network, Inc.
5	6/3/2021 3:14:53 PM	Attorney Listed	P-001	A-10259 - John Hague Bryan
6	6/3/2021 3:14:53 PM	Service Requested	D-001	Secretary of State - Certified - Other Country - Including Copy Fee
7	6/4/2021 8:41:07 AM	Document Emailed		Court user emailed krista.ford@steptoe-johnson.com document 1-2 - Complaint - Complaint
8	6/4/2021 8:43:30 AM	Document Emailed		Court user emailed krista.ford@steptoe-johnson.com document 1-3 - Supporting Document - Exhibits A-E
9	6/4/2021 10:26:41 AM	Style Assigned		Stephanie McCutcheon v. Enlivant ES, LLC, a foreign limited liability company, d/b/a Seasons Place Assisted Living Facility, Corporate Creations Network, Inc.
10	6/4/2021 10:32:40 AM	Style Assigned		Stephanie McCutcheon v. Enlivant ES, LLC, a foreign limited liability company, d/b/a Seasons Place Assisted Living Facility
11	6/22/2021 4:08:46 PM	E-Docketed		Service Return - Return from Sec. of State.
	11-1 6/16/2021	Service Return - Return from Sec. of State.		
	11-2 6/16/2021	Transmittal		
12	6/22/2021 5:36:24 PM	E-Filed		Notice of Appearance - Notice of Entry of Appearance of Bethany S. Wagner
	12-1 6/22/2021	Notice of Appearance - Notice of Entry of Appearance for Bethany S. Wagner		
	12-2 6/22/2021	Transmittal		
13	6/22/2021 5:36:24 PM	Attorney Listed	D-001	A-11341 - Bethany Swaton Wagner

IN THE CIRCUIT COURT OF GREENBRIER COUNTY, WEST VIRGINIA

STEPHANIE MCCUTCHEON,

Plaintiff,

v. Civil Action No. _____

ENLIVANT ES, LLC, a foreign limited liability company, d/b/a SEASONS PLACE ASSISTED LIVING FACILITY,

Defendant.

COMPLAINT

Comes now the Plaintiff, Stephanie McCutcheon, and for her Complaint, alleging retaliatory discharge, pursuant to the exception to at-will employment created under Harless v. First National Bank, 162 W.Va. 116, 246 S.E.2d 270 (1978), as well as declaratory and injunctive relief, states as follows:

1. Plaintiff, Stephanie McCutcheon, is a West Virginia resident residing in Greenbrier County, West Virginia.

2. Defendant, Enlivant ES, LLC is a foreign limited liability company with a principal office address 330 N. Wabash Ave, STE 3700, Chicago, IL 60611 and a notice of process address of Corporate Creations Network, Inc., 126 East Burke Street, Martinsburg, WV 25401 and doing business as Seasons Place Assisted Living Facility in Lewisburg, Greenbrier County, West Virginia.

3. This Court has jurisdiction over this action pursuant to West Virginia Code § 51-2-1, et seq.

4. Venue is proper in Greenbrier County, West Virginia, pursuant to West Virginia Code § 56-1-1(a)(1), as it is the location of the events alleged herein, as well as

the county of residence of the Plaintiff, and also the county where defendant operates the facility which employs the Plaintiff.

STATEMENT OF FACTS

5. Plaintiff, Stephanie McCutcheon, was employed at an assisted living facility doing business as Seasons Place Assisted Living, located in Lewisburg, Greenbrier County, West Virginia. She was so employed for approximately 5 years.

6. On or about April 14, 2021, Sherry Shires, defendant's executive director for Seasons facility, provided a letter to the staff at The Seasons which communicated that the defendant had an "expectation" that all employees at The Seasons would be vaccinated with one of the COVID-19 vaccines no later than June 1, 2021.

7. Sherry Shires engaged in numerous conversations with the Plaintiff, attempting to convince her to get the vaccine, representing to her falsely that the vaccine was approved by the FDA and assuring her that the vaccine was safe.

8. However, Plaintiff had performed her own research on the vaccines for COVID-19 and had determined that the appropriate personal medical decision for her was to not take the COVID-19 vaccine.

9. Plaintiff continued to protest to her employer that she felt strongly that she could not, and would not, get the vaccine. She reached out to Human Resources, which is based out of Chicago.

10. Initially, Human Resources in Chicago would only advise Plaintiff verbally that it was mandatory for the Plaintiff to be vaccinated for COVID-19. Plaintiff requested the same in writing. However, HR initially refused.

11. Eventually, as June 1, 2021 approached, Plaintiff received a letter from HR, dated May 25, 2021, which read as follows:

> May 25, 2021
>
> Re: **Voluntary Resignation Due to Personal Choice to Remain Unvaccinated**
>
> Dear Employee,
>
> As you know, leading authorities now instruct that vaccination is the most effective method to combat the spread of COVID-19 and minimize its impacts. Similarly, our experience has shown that being unvaccinated puts at risk the safety and well-being, and lives of our residents, employees and visitors, and has a significant impact on our daily business operations. As such, to best protect our residents, employees, and visitors, Enlivant determined that beginning June 1, 2021, all Enlivant employees at your Community must be vaccinated.
>
> **Therefore, due to your personal choice to remain unvaccinated contrary to the essential functions of your job and Enlivant's job requirements, we are accepting your voluntary resignation effective June 1, 2021**....[1]
>
> Best wishes,
>
> Andrew Knuth
> Human Resources Director
> Enlivant Senior Living

(Exhibit "A", May 25, 2021 letter from Andrew Knuth).

12. Indeed, on June 1, 2021, Plaintiff was discharged from employment.

13. Plaintiff did not resign from her employment and consistently communicated to her employer that she refused to voluntarily resign.

[1] Emphasis original. See May 25, 2021 letter from Andrew Knuth, attached hereto as Exhibit "A."

COVID-19 VACCINE IS NOT APPROVED BY THE FDA

14. On December 11, 2020, the United States Food and Drug Administration ("FDA") issued the first emergency use authorization ("EAU") for an experimental vaccine for the prevention of coronavirus disease 2019 ("COVID-19"). Emergency use authorization is not an FDA approval. The experimental vaccine has been in existence for less than a year. The first reported use of the experimental vaccine was December 14, 2020.

15. It is undisputed that the vaccine being forced upon Plaintiff is "unapproved". Even though the FDA granted emergency use authorization for the Pfizer/BioNTech and Moderna vaccines in December 2020, the clinical trials the FDA will rely upon to ultimately decide whether to license these and other COVID-19 experimental vaccines are still underway and are designed to last for approximately two (2) years to collect adequate data to establish if these vaccines are safe and effective enough for the FDA to approve. The abbreviated timelines for the emergency use applications and authorizations means there is much the FDA does not know about these products even as it authorizes them for emergency use, including their effectiveness against infection, death, and transmission of SARS-CoV-2, the virus that is allegedly the cause of the COVID disease. Given the uncertainty about the COVID-19 experimental vaccines, the FDA requires that each dose of the experimental vaccine shall have a label that states that the product is an emergency use authorization, that the EAU is explicit that each is "an investigational vaccine not licensed for any indication" and that all "promotional material relating to the Covid-19 Vaccine clearly and conspicuously...state that this product has not been approved or licensed by the FDA,

but has been authorized for emergency use by FDA". (Exhibit "B", EAU letter for Pfizer). The Fact Sheet for vaccination providers and recipients, as mandated by the FDA, is required to be made available to vaccination providers and recipients of the vaccine, and warns that recipients should mention certain medical conditions and circumstances to vaccination providers before getting the vaccine, such as those with bleeding disorders, taking blood thinners, those who are immunocompromised, etc. The fact sheet also requires a warning that certain individuals should **NOT** get the vaccine (emphasis original), such as those who have had a severe allergic reaction to any ingredient of the vaccine. (Exhibit "C", Fact Sheet for Recipients and Caregivers).

16. The FDA on their website has stated the following:

> "FDA believes that terms and conditions of an EAU issued under section 564 preempt state or local law, both legislative requirement and common-law duties, that impose different or additional requirements on the medical product for which the EAU was issued in the context of the emergency declared under section 564... In an emergency, it is critical that the conditions that are part of the EAU or an order or waiver issued pursuant to section 564A – those that FDA has determined to be necessary or appropriate to protect the public health-be strictly followed, and no additional conditions be imposed."[2]

17. In August 2020, the Centers for Disease Control and Prevention ("CDC") published a meeting of the Advisory Committee on Immunizations and Respiratory Diseases, Dr. Amanda Cohn stated (@1:14:40):

> "I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EAU, vaccines are not allowed to be mandatory. So, early in the vaccination phase, individuals will have to be consented and they won't be able to be mandated."

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[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

18. Here, Plaintiff has been terminated from her job and other employees in West Virginia are in imminent and immediate danger of being terminated from their jobs for refusing to take an experimental vaccine that is being provided under an EUA.

THE RUSH TO FIND AN EXPERIMENTAL COVID-19 VACCINE

19. On January 30, 2020, the World Health Organization ("WHO") declared a "public health emergency of international concern over the global outbreak" of COVID-19. Among other recommendations, WHO called for the accelerated development of "vaccines", therapeutics and diagnostics." The following day, U.S. Health and Human Services ('HHS") Secretary, Alex Azar, declared a national Public Health Emergency ("PHE") retroactive to January 27, 2020, "to aid the nation's healthcare community in responding" to COVID-19. By then, HHS was already collaborating with the pharmaceutical industry regarding the development of vaccines.

20. In April 2020, the national Administration announced Operation Warp Speed ("OWS") – a public/private partnership to develop and distribute a vaccine for COVID-19 by the end of 2020 or early 2021. The process for developing a vaccine normally takes place in several phases, over a period of years.

21. The general stages of the development cycle for a vaccine are:

a. Exploratory stage;
b. Pre-clinical stage (animal testing);
c. Clinical development (human trials - see below);
d. Regulatory review and approval;
e. Manufacturing; and
f. Quality control.[3]

[3] https://www.cdc.gov/vaccines/basics/test-approve.html

22. The third stage, clinical development, is itself a three-phase process:

a. During Phase I small groups of people receive the trial vaccine.

b. In Phase II, the clinical study is expanded and the vaccine is given to people who have characteristics (such as age and physical health similar to those for whom the new vaccine is intended.

c. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety.

23. Phase III itself normally occurs over a course of years because it can take years for the side effects of a new vaccine to manifest themselves. Phase III must be followed by a period of regulatory review and approval. During this stage, data and outcomes are reviewed by peers and by the FDA. Finally, the manufacturer must demonstrate that the vaccine can be manufactured under conditions that assure adequate quality control.

24. The timeline set by OWS telescoped what would normally take years of research into a matter of months. Commercial vaccine manufacturers and other entities proceeded with the development of COVID-19 vaccine candidates using different technologies including RNA, DNA, protein, and viral vectored vaccines. Two potential vaccines emerged early on as likely candidates: one developed by Moderna ("Moderna Vaccine") and the other by Pfizer ("Pfizer Vaccine") with both announcing Phase III trial results in November 2020. In early 2021, Janssen Biotech, Inc., submitted Phase III trial results for its adenovirus vector vaccine ("Janssen Vaccine").

VAERS DATABASE IDENTIFIES SERIOUS COVID-19 HEALTH CONCERNS

25. In 1990, the Vaccine Adverse Event Reporting Systems ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines.[4] VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern.

26. There were 4,434 death reports and over 12,619 serious injuries reported to the CDC's VAERS database from COVID-19 vaccines through May 10, 2021. By comparison, from July 1, 1997, until December 31, 2013, VAERS received 666 adult death reports.[5] The flu vaccines are linked to 20–30 death reports a year, according to Dr. Peter McCullough[6], and those 20–30 death reports come with considerably more vaccines administered.[7] Arguably, if the experimental vaccine was any other vaccine or

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[4] VAERS is co-managed by the CDC and the FDA. VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

[5] Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015)

[6] Dr. McCullough is vice chief of medicine at Baylor University Medical Center and the most cited American medical doctor on COVID-19 at the National Library of Medicine.

[7] Dr. McCullough estimated the flu shot at 195 million people annually, while over 153 million have currently received COVID vaccinations. The disparity between these two vaccine groups is staggering.

drug, it would already have been removed from the market. Usually, a new drug is withdrawn after 50 deaths, which is not typical because the FDA has a strict approval process. The COVID-19 vaccines have been exempted from the approval process, instead being temporarily "authorized" for emergency use.

27. Thirty-five hundred plus (3,500 +) reports is 70 times the normal threshold for pulling a drug from the market. Although this is raw data, previous VAERS studies have shown that only 1-10% of vaccine-related deaths are reported to VAERS —or less. The COVID vaccines are adding a year's worth of VAERS reports every week. In just four months, more adverse reports were added to the VAERS database than any single vaccine has had cumulatively over the past 31 years. This is clearly a safety signal, further studies need to be done and Plaintiff should not be forced to participate in these dangerous trials as a condition for employment.

EXPERIMENTAL COVID-19 VACCINES HAVE NOT RECEIVED FINAL APPROVAL FROM THE FDA, YET PLAINTIFF WAS NOT GIVEN A CHOICE ON WHETHER SHE WANTED TO PARTICIPATE IN THE EXPERIMENTAL TRIAL

28. None of the currently available experimental vaccines for COVID-19 has received final approval from the FDA. Rather, each one of the COVID-19 experimental vaccines is an unapproved product that has been granted EAU. The FDA refers to the COVID-19 experimental vaccine as “investigational products”, meaning they remain classified as experimental.

29. The statute granting the FDA the power to authorize a medical product for emergency use requires that the person being administered the unapproved product be advised of his and her right to refuse administration of the product. *See* 21 U.S.C. §

360bbb-3(e)(1)(A) ("Section 360bbb-3"). Additionally, terms and conditions of EAUs preempt state and local laws that would impose obligations that are inconsistent with those terms and conditions. Here, the defendant does not inform Plaintiff of her right to refuse administration of the experimental vaccine. In fact, Plaintiff is not given a choice as to whether or not she wants to participate in the experimental vaccine trials. The only choice the Plaintiff has is to join the experimental trial and be injected with the experimental vaccine or be fired.

LONG STANDING PUBLIC POLICY AGAINST FORCING PLAINTIFF TO PARTICIPATE IN A VACCINE TRIAL

30. Section 360bbb-3 reflects a fundamental, public policy goal of striking a balance between giving people the option of having access to experimental medical products during public emergencies, while also assuring that no one is forced to accept administration of such and the experimental medical product. Section 360bbb—further recognizes the well-settled doctrine that medical experiments, better known in modern parlance as "clinical research", may not be performed on human subjects without the express, informed consent of the individual receiving treatment. This right to avoid the imposition of human experimentation is fundamental and has its roots in the Nuremberg Code of 1947[8] and has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations.

[8] The Nuremberg Code is a medical ethics code issued based on laws under which the Nazi criminals were judged for conducting horrible medical experiments during the Second World War, in the physicians' trial known by the name Nuremberg Trial. The Nuremberg Code later constituted the base for the Helsinki Declaration Legislation.

THE UNIVERSAL PROHIBITION ON HUMAN EXPERIMENTATION WITHOUT CONSENT

31. Among the horrors that emerged from the rubble of World War II were stories of barbaric medical experiments performed on unwilling victims of Nazi Germany's concentration camps. On August 8, 1945, the prevailing Allies established an International Military Tribunal ("IMT"). Under the aegis of the IMT, the creation of U.S. military tribunals for the trial of "lower- level" war criminals, such as doctors accused of conducting medical experiments without the subject's consent was authorized.[9] A U.S. military tribunal subsequently found 15 doctors guilty of conducting nonconsensual experiments, which included the testing of drugs for immunizations against malaria, epidemic jaundice, smallpox, and cholera. "In every single instance appearing in the record," the tribunal concluded, "subjects were used who did not consent to the experiments." The tribunal sentenced seven of the doctors to death and the remaining eight to life in prison. As part of its final judgement, the tribunal promulgated the Nuremberg Code on Permissible Medical Experiments.

32. Point One of the Nuremberg Code states: "The voluntary consent of the human subject is absolutely essential." This standard has since been repeatedly ratified and adopted around the globe, in laws, treaties, regulations, and ethical guidelines for medical research. For example, in 1964, the World Medical Association adopted the Declaration of Helsinki, which provides that human subjects "must be volunteers and informed participants in the research project." Declaration of Helsinki at Art. 20.

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[9] Sources for the historical facts set forth herein can be found in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009), which explains in detail the history and the reason why the prohibition against nonconsensual human experimentation should be regarded as a jus cogens norm.

33. For these and other reasons, the prohibition against nonconsensual human experimentation must be regarded not only as established by U.S. law and regulations, but also as broadly recognized by all nations as to constitute a *jus cogens* norm under international law.

SPIKE PROTEIN RESEARCH DEVELOPING-IMPACT ON HOST CELLS ARE UNKNOWN - MORE STUDIES ARE NEEDED

34. The experimental SARS-CoV-2 vaccine contains laboratory synthesized mRNA in a lipid package. This mRNA enters the host's cells and hijacks the cells, causing them to produce the spike protein of the coronavirus, which elicits the development of antibodies.[10] The human host cells respond to the spike protein and elicit cell signaling.[11] The spike protein produced by the new COVID-19 experimental vaccines may also affect the host cells.[12] Scientists recommend that we monitor the long-term consequences of these experimental vaccines carefully, especially when they are administered to otherwise healthy individuals.[13] Scientists further conclude that

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[10] Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells:
Implications for Possible Consequences of COVID-19 Vaccines. Vaccines (Basel). 2021;9(1):36. Published 2021 Jan 11. doi:10.3390/vaccines9010036

[11] Id.

[12] Id.

[13] Id.

further investigations on the effects of the SARS-CoV-2 spike protein on human cells and appropriate experimental animal models are warranted.[14]

35. A recent study suggests that the SARS-CoV-2 spike protein can by itself trigger cell signaling that can lead to various biological processes.[15] The scientists who conducted the study concluded, "It is reasonable to assume that such events, in some cases, result in the pathogenesis of certain diseases."[16] Despite the experimental nature of the vaccine and the numerous adverse side effects related to the experimental vaccine including, but not limited to, death through anaphylactic shock[17], thrombosis

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[14] Id. ("However, we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.")

[15] Id.

[16] Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. Vaccines (Basel). 2021;9(1):36. Published 2021 Jan 11. doi:10.3390/vaccines9010036.

[17] Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine-United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep 2021; 70:46-51. DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1.

with thrombocytopenia syndrome[18], blood clots, multi-system autoimmune disorders and multi-organ failure[19], and the fact that some scientists have concluded that it is reasonable to assume the experimental vaccine will result in the pathogenesis of certain diseases.

36. The defendant's Human Resources Director gave employees, including the Plaintiff, an ultimatum - if you want to keep your job, continue to feed your family, and avoid bankruptcy, you must be injected with the experimental COVID-19 vaccine.

COUNT ONE - RETALIATORY DISCHARGE

37. The previous paragraphs are hereby incorporated by reference as though fully restated herein.

38. Seeking to temper the otherwise harsh results that would obtain where a discharge from employment was impelled by the employer's desire to contravene public

[18] Safety monitoring of the J&J/Janssen vaccine suggests a risk of an adverse event called thrombosis with thrombocytopenia syndrome (TTS), which involves blood clots with low platelets. Platelets are a type of blood cell that help blood clot. On April 13, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) suggested pausing administration of the AD26.COV2.S Johnson & Johnson (JJ) vaccine to allow investigation of several cases of a severe thrombosis with thrombocytopenia occurring post- vaccination. This announcement came on the heels of the initial reports of similar events in individuals receiving the CHaDOx1 nCov-19 AstraZeneca (AZ) vaccine outside the United States. Clinical and laboratory characteristics of TTS have recently been reported. This syndrome has been termed "vaccine-induced prothrombotic immune thrombocytopenia (VIPIT)" or "vaccine- induced immune thrombotic thrombocytopenia (VITT)" but is now termed "thrombosis with thrombocytopenia syndrome (TTS)" by the CDC and FDA. James B. Bussel, MD et al., American Society of Hematology, Thrombosis with Thrombocytopenia Syndrome (also termed Vaccine- induced Thrombotic Thrombocytopenia), April 29, 2021.

[19] Id.

policy, an exception to the common law doctrine of at-will employment was established.[20]

39. That exception, created in Harless v. First National Bank, 162 W.Va. 116, 246 S.E.2d 270 (1978), provides:

> The rule that an employer has an absolute right to discharge an at will employee must be tempered by the principle that where the employer's motivation for the discharge is to contravene some substantial public policy principle, then the employer may be liable to the employee for damages occasioned by this discharge.[21]

40. The West Virginia Supreme Court has identified the areas from which public policy may be gleaned:

> " 'The sources determinative of public policy are, among others, our federal and state constitutions, our public statutes, our judicial decisions, the applicable principles of the common law, the acknowledged prevailing concepts of the federal and state governments relating to and affecting the safety, health, morals and general welfare of the people for whom government—with us—is factually established.' "[22]

41. "To identify the sources of public policy for purposes of determining whether a retaliatory discharge has occurred, we look to established precepts in our constitution, legislative enactments, legislatively approved regulations, and judicial opinions."[23]

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[20] *See* Frohnapfel v. ArcelorMittal USA LLC, 235 W.Va. 165, 772 S.E.2d 350 (W. Va. 2015); *See also* Wright v. Standard Ultramarine and Color Co., 141 W.Va. 368, 382, 90 S.E.2d 459, 468 (1955) (recognizing that at- will employees serve at will and pleasure of their employers and may be discharged at any time, with or without cause).

[21] Id. at 116, 246 S.E.2d at 271, syllabus; Frohnapfel v. ArcelorMittal USA LLC, 235 W.Va. 165, 772 S.E.2d 350 (W. Va. 2015).

[22] Birthisel v. Tri–Cities Health Services Corp., 188 W.Va. 371, 376, 424 S.E.2d 606, 611 (1992); Frohnapfel v. ArcelorMittal USA LLC, 235 W.Va. 165, 169 (W. Va. 2015).

[23] Syl. Pt. 2, Birthisel, 188 W.Va. at 372, 424 S.E.2d at 607.

42. "Substantial public policy" has been defined by the Supreme Court as "not just recognizable as such but be so widely regarded as to be evident to employers and employees alike."[24] The Court recognized in Syllabus Point 3 of Birthisel that ""[i]nherent in the term 'substantial public policy' is the concept that the policy will provide specific guidance to a reasonable person."[25] The Court has looked to whether regulations or licensing statutes contained specific provisions that addressed the allegedly improper conduct by the employer.[26]

43. The Mandatory COVID-19 Vaccination Directive issued by the Defendant is in direct violation of Federal law, specifically 21 U.S. Code § 360bbb-3 – Authorization for medical products for use in emergencies. That law states that where a medical product is "unapproved" then no one may be mandated to take it. At Section (e)(1)(A) of the aforementioned statute it states:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> > (i) Appropriate conditions designed to ensure that the health care professionals administering the product are informed –
> >
> > (ii) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

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[24] Id. at 745, 559 S.E.2d at 718.

[25] 188 W.Va. at 372, 424 S.E.2d at 607.

[26] Frohnapfel v. ArcelorMittal USA LLC, 235 W.Va. 165, 170 (W. Va. 2015).

> (iii) of the alternatives to the product that are available, and of their benefits and risks.
>
> (iv) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
>
> (v) that the Secretary has authorized the emergency use of the product;
>
> (vi) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (vii) **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks (emphasis added)

44. The Defendant violated at least two quoted sections (ii and iii). The Defendant did not advise Plaintiff of the "known and potential benefits and risks of such emergency use of the product, and of the extent to which such benefits and risks are unknown" of the COVID-19 experimental vaccine. Additionally, Plaintiff was not provided "the option to accept or refuse administration of the..." experimental vaccine as a condition for employment. Plaintiff communicated this information to her employer, as evidenced by a letter dated May 4, 2021, wherein she specifically cited Section 360bbb-3 and the provision forbidding the mandating of the vaccine. (Exhibit "D" - May 4, 2021 Letter from Plaintiff). In response, Plaintiff received a letter from Defendant dated May 7, 2021 from Nate McBride, Senior Human Resources Manager, which stated as follows:

> Hi Stephanie,
>
> Thank you for reaching out - I just left you a voicemail to discuss. Sherry is correct in her guidance. Enlivant has a duty to provide a safe and healthy work environment for our vulnerable senior citizen residents and valued team members. Public health experts advise that vaccination is the most effective way to combat the spread of the deadly COVID-19 virus and minimize its impacts. To best protect our residents, employees,

> and visitors, all Enlivant employees must be vaccinated or have an approved accommodation.
>
> If you have any questions or would like to discuss this further, please don't hesitate to reach out to me.
>
> Best wishes,
>
> Nate McBride
> Senior Human Resources Manager
> Enlivant

(Exhibit "E" - May 7, 2021 Letter from Nate McBride). Thereafter Plaintiff was discharged in retaliation for her refusal to take the unapproved and non-mandatory vaccine, as well as for her insistence that defendant comply with existing federal law and public policy. Such conduct is in violation of a substantial public policy of this state, as defined by the State Supreme Court, and is the basis for an exception to the at-will employment doctrine.

45. The federal statutes and regulations discussed herein are sufficient so as to provide guidance to a reasonable person to understand that non-mandatory unapproved vaccines should not be mandated by employers in West Virginia - especially after more than 1.5 years have elapsed since the event giving rise to the emergency which formed the basis of the emergency use authorization occurred.

46. Plaintiff suffered damages in an amount in excess of the minimum jurisdictional limits of the Court.

47. Defendants' wrongful acts have caused injury to Plaintiff. Plaintiff has suffered lost wages, loss of earnings capacity, lost benefits, lost future earnings, mental anguish, inconvenience, and loss of enjoyment of life as a direct result of Defendants' unlawful actions against them. Plaintiff suffered these injuries as the result of

Defendants' actions and in all reasonable probability will continue to suffer these injuries in the future. Plaintiff also seeks punitive damages as the result of Defendants' malicious, reckless condition surrounding Plaintiff's termination.

COUNT TWO - DECLARATORY RELIEF

48. The previous paragraphs are hereby incorporated by reference as though fully restated herein.

49. This is a cause of action pursuant to West Virginia Code Section 55-13-1, to obtain a declaration of rights regarding whether a private employer in West Virginia, such as the defendant, can mandate the unapproved non-mandatory COVID-19 vaccine for employee, such as is the subject of this action.

50. The Plaintiff asserts that this action involves a present justiciable controversy sufficient to support a claim pursuant to the Uniform Declaratory Judgments Act, West Virginia Code Section 55-13-1, *et seq*.

51. The Plaintiff asserts that she has been wrongfully discharged in violation of state and federal law, as outlined herein and that she is entitled to have this Court advise as to the interests of the parties herein.

52. The Plaintiff has no adequate remedy at law.

COUNT THREE - PETITION FOR INJUNCTIVE RELIEF, INCLUDING MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

53. The previous paragraphs are hereby incorporated by reference as though fully restated herein.

54. Plaintiff was threatened with discharge and ultimately discharged for choosing not to take an FDA unapproved experimental vaccine which federal law states cannot be mandated because insufficient trials have been conducted and its long-term effects are not known. Currently there are many new reports of adverse effects and even deaths resulting from the experimental vaccine. Plaintiff was terminated for refusing to take an experimental vaccine which federal law states cannot be mandated, constitutes a retaliatory discharge under West Virginia law.

55. Pursuant to Rule 65(a) of the West Virginia Rules of Civil Procedure, the petitioner hereby moves for a preliminary injunction. Plaintiff asserts that there exists the reasonable likelihood of irreparable harm to the Plaintiff, and others similarly situated, without the injunction; that there is no reasonable likelihood of harm to the defendant by being required to comply with federal law; that Plaintiff is likely to succeed on the merits of the underlying claim; and that the public interest is served in requiring the defendant to comply with existing public policy and federal law.

56. Therefore, Plaintiff respectfully requests this Court issue a preliminary injunction, after notice and hearing, restraining the Defendant, their agents, representatives, or anyone acting on their behalf until further order of the Court from terminating Plaintiff for the sole reason of their refusal to be injected with the experimental COVID-19 vaccine, as well as ordering and directing the defendant to re-employ Plaintiff at her previous position of employment.

57. The Plaintiff/petition requests an expedited hearing on the petition for preliminary injunction, given the time sensitive nature of the circumstances, including

both the financial harm being incurred daily by the Plaintiff, as well as the potential for other similar situated people to be forcibly mandated in violation of federal law.

58. The Plaintiff/petitioner is prepared to post security in such sum as the court in its discretion deems proper.

59. The Plaintiff/petitioner has no other adequate remedies at law.

PRAYER

WHEREFORE, the Plaintiff respectfully prays for the following relief:

1. That the Court schedule this matter for an expedited hearing for a preliminary injunction enjoining the defendant from terminating employees, including the Plaintiff, for refusing to take a non-mandatory, unapproved vaccine, and to direct that Plaintiff be immediately reinstated to her employment; and

2. That the Court declare and decree that the defendant may not terminate or take negative action against an employee for refusing to take a non-mandatory, unapproved vaccine; and

3. That the Court award the Plaintiff damages, as well as reasonable attorney fees and expenses for the retaliatory discharge of the Plaintiff; and

4. That the Court award punitive damages against the defendant; and

5. For such other and further relief as the Court deems just and fit.

PLAINTIFF DEMANDS A TRIAL BY JURY FOR ALL CLAIMS SO-TRIABLE

STEPHANIE MCCUTCHEON
By Counsel

/s John H. Bryan
John H. Bryan (WV Bar No. 10259)
411 Main Street
P.O. Box 366
Union, WV 24983
jhb@johnbryanlaw.com
(304) 772-4999
Fax: (304) 772-4998

Exhibit A

Enlivant

May 25, 2021

Re: **Voluntary Resignation Due to Personal Choice to Remain Unvaccinated**

Dear Employee,

As you know, leading authorities now instruct that vaccination is the most effective method to combat the spread of COVID-19 and minimize its impacts. Similarly, our experience has shown that being unvaccinated puts at risk the safety, well-being, and lives of our residents, employees, and visitors, and has a significant negative impact on our daily business operations. As such, to best protect our residents, employees, and visitors, Enlivant determined that beginning June 1, 2021, all Enlivant employees at your Community must be vaccinated.

Therefore, due to your personal choice to remain unvaccinated contrary to the essential functions of your job and Enlivant's job requirements, we are accepting your voluntary resignation effective June 1, 2021.

If you are COBRA eligible, information will come under separate cover directly from our third-party administrator.

Naturally, should your personal stance change, and you become vaccinated in the future, you may apply for any open and available position for which you are qualified.

We wish you well in your future endeavors,

Best wishes,

Andrew Knuth
Human Resources Director
Enlivant Senior Living

Where Senior Living Thrives™

330 N. Wabash Suite 3700 | 312-725-7000
Chicago, Illinois 60611 | 312-332-5300 f

Enlivant.com

Exhibit B

May 10, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization twice: December 23, 2020[3] and February 25, 2021.[4]

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

On May 10, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA again is reissuing the letter in its entirety to authorize emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. With authorization of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) is being revised to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." The Fact Sheet for Recipients and Caregivers is being revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

Pfizer-BioNTech COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or

saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[5]

II. Scope of Authorization

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s)[6], to emergency response stakeholders[7] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[8] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

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[6] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[7] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[8] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 12 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the Pfizer COVID-19 Vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for

Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[9]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

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[9] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due July 2021.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in children and adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:
   - This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
   - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

Exhibit C

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 12 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?
You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?
The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-4.2a
Revised: 10 May 2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 05/2021

Exhibit D

Date: May 4, 2021
To: Whom It May Concern:
Re: Covid-19 Experimental Vaccine Candidates

Any compulsory Covid-19 vaccination requirement is a violation of federal law. I urge you to advise all employees that they have the right to refuse or to take any COVID-19 vaccine. Any other action is contrary to federal law.

Covid-19 Vaccines are Experimental.

Covid-19 vaccines are not approved by the FDA. The Covid-19 vaccines are only approved under an Emergency Use Authorization, for investigational use only.[1] Covid-19 vaccines lack requisite studies and are not approved medical treatment. The FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances … That they have the option to accept or refuse the EUA product …"[2]

Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") vests the Secretary of Health and Human Services with the permissive authority to grant Emergency Use Authorizations ("EUAs") providing that appropriate conditions designed to ensure that individuals to whom the product is administered are informed:

1. that the Secretary has authorized the emergency use of the product;

2. of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

3. **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. [1]

The right to avoid the imposition of human experimentation is fundamental, rooted in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations. In addition to the United States regarding itself as bound by these provisions, these principles were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. It is unlawful to conduct medical research, even in the case of an emergency, unless steps are taken to secure **informed consent** of all participants.[3]

The following Emergency Use Authorizations have been issued for Covid-19 vaccinations:

12/11/20 Moderna - FDA issued an EUA for emergency use of the Moderna mRNA COVID-19 vaccine for recipients 16 years of age or older.

12/18/20 Pfizer/BioNTech - FDA issued an EUA for emergency use of the Pfizer/BioNTech mRNA vaccine for recipients 18 years of age or older.

2/27/21 Johnson & Johnson - FDA issued an EUA for emergency use of the Johnson & Johnson COVID-19 vaccine (aka Janssen vaccine) for recipients 18 years of age or older.

Each of the above EUAs was issued in conjunction with a similar Fact Sheet from the FDA. For example, the Janssen fact sheet contains the following notice:

> **"INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS"**
> As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website to obtain the Fact Sheet) prior to the individual receiving the Janssen Covid-19 Vaccine, including:
>
> - FDA has authorized the emergency use of the Janssen Covid-19 Vaccine, which is not an FDA approved vaccine.
> - ***The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.***
> - The significant known and potential risks and benefits of the Janssen Covid-19 Vaccine, and the extent to which such risks and benefits are unknown.[4]

Clearly, any attempt to force anyone to take a Covid-19 vaccine is a violation of federal law and the conditions under which the Covid-19 vaccine has been authorized for use. The law is clear, experimental medical treatment cannot be mandated.

Businesses are not shielded from liability with experimental agents.

Under the 2005 PREP Act enacted by Congress, pharmaceutical companies that manufacture EUA vaccines are shielded from liability related to injuries and damages caused by their experimental agents. However, any employer, public school, or any other *entity or person* who mandates experimental vaccines on any human being is not protected from liability for any resulting harm. While vaccine manufacturers may be shielded from liability, your institution is not protected, and neither are you.[5]

You are hereby on notice that if you illegally or irresponsibly mandate EUA medical therapies on employees, such as the experimental Covid-19 vaccine candidates, I may have no choice but to take legal action, and you may be personally liable for resulting harm.

I urge Enlivant to comply with the FD&C Act and the terms of the EUA and its accompanying Fact Sheet, and to advise all employees of their right to accept *or refuse* any Covid-19 vaccine. Any other course of action is contrary to federal law.

Thank you for your time and for protecting the best interest of your employees.

Sincerely,

Stephanie McCutcheon

[1] https://ca.childrenshealthdefense.org/wp-content/uploads/CDE-Superintendent-Letter0from-Childrens-Health-Defense-California-Chapter.pdf

[2] https://www.fda.gov/media/97321/download

[3] 21 CFR § 50.24

[4] www.janssencovid19vaccine.com

[5] https://childrenshealthdefense.org/defender/under-federal-law-can-your-employer-make-you-get-covid-vaccine/

Exhibit E

ISSUE TYPE:
HOSTILE WORK ENVIRONMENT

Add Follow-Up NotesUpload Files
Report Details
Print My Report
Join a Chat
Log Off

QUESTIONS AND COMMENTS

Answer questions about your report.
5/7/2021 10:21 AM

Hi Stephanie,

Thank you for reaching out - I just left you a voicemail to discuss. Sherry is correct in her guidance. Enlivant has a duty to provide a safe and healthy work environment for our vulnerable senior citizen residents and valued team members. Public health experts advise that vaccination is the most effective way to combat the spread of the deadly COVID-19 virus and minimize its impacts. To best protect our residents, employees, and visitors, all Enlivant employees must be vaccinated or have an approved accommodation.

If you have any questions or would like to discuss this further, please don't hesitate to reach out to me.

Best wishes,

Nate McBride
Senior Human Resources Manager
Enlivant
(312) 725-7166
nmcbride@enlivant.com

Stephanie McCutcheon

v.

Enlivant ES, LLC, d/b/a Seasons Place Assisted Living Facility

EXHIBIT B

IN THE CIRCUIT COURT OF GREENBRIER COUNTY, WEST VIRGINIA

STEPHANIE MCCUTCHEON, Plaintiff, v. ENLIVANT ES, LLC, a foreign limited liability company, d/b/a SEASONS PLACE ASSISTED LIVING FACILITY, Defendant.	)	Civil Action No. CC-13-2021-C-48

NOTICE OF FILING OF NOTICE OF REMOVAL TO FEDERAL COURT

PLEASE TAKE NOTICE that on July 9, 2021, Defendant Enlivant ES, LLC ("Defendant") (incorrectly named in the Complaint as Enlivant ES, LLC, d/b/a Seasons Place Assisted Living Facility) caused this action to be removed to the United States District Court for the Southern District of West Virginia. This notice is being provided pursuant to 28 U.S.C. § 1446(d). A copy of the Notice of Removal filed in the United States District Court for the Southern District of West Virginia is attached hereto as Exhibit 1 and incorporated herein by reference.

RESPECTFULLY, PLEASE TAKE FURTHER NOTICE that, pursuant to 28 U.S.C. § 1446(d), the filing of the Notice of Removal in the United States District for the Southern District of West Virginia and the filing of this Notice effectuate the removal of this action, and this Court may proceed no further unless and until the case is remanded.

Dated: July 9, 2021

Respectfully submitted,

OGLETREE, DEAKINS, NASH,
SMOAK & STEWART, P.C.

By: */s/Bethany S. Wagner*

Bethany S. Wagner
WV 11341
One PPG Place, Suite 1900
Pittsburgh, Pennsylvania 15222
412-315-6040
bethany.wagner@ogletree.com

Attorney for Defendant

Stephanie McCutcheon

v.

Enlivant ES, LLC, d/b/a Seasons Place Assisted Living Facility

Civil Action No. CC-13-2021-C-48

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

STEPHANIE MCCUTCHEON, Plaintiff, v. ENLIVANT ES, LLC, a foreign limited liability company, d/b/a SEASONS PLACE ASSISTED LIVING FACILITY, Defendant.	)	Civil Action No. (formerly Civil Action No. CC-13-2021-C-48 in the Circuit Court of Greenbrier County)

DEFENDANT ENLIVANT ES, LLC D/B/A SEASONS PLACE ASSISTED LIVING FACILITY'S NOTICE OF REMOVAL

Under 28 U.S.C. §§ 1332, 1441, and 1446 Defendant Enlivant ES, LLC ("Defendant") (incorrectly named in the Complaint as Enlivant ES, LLC d/b/a Seasons Place Assisted Living Facility) gives Notice of Removal of the above-captioned matter, Civil Action No. CC-13-2021-C-48, formerly pending in the Circuit Court of Greenbrier County, West Virginia, to the United States District Court for the Southern District of West Virginia. In support of removal, Defendant states as follows:

I. Factual Background

1. On or about June 3, 2021, Plaintiff Stephanie McCutcheon ("Plaintiff") filed a civil action against Defendant in the Circuit Court of Greenbrier County, West Virginia.

2. The complaint was served on Defendant via the West Virginia Secretary of State as attorney-in-fact on June 9, 2021.

3. Defendant has timely filed this notice of removal within thirty (30) days of receipt of Plaintiff's Complaint.

4. Plaintiff's Complaint purports to set forth a claim alleging retaliatory discharge in contravention of public policy as recognized in *Harless v. First Nat. Bank of Fairmont*, 246 S.E.2d 270 (1978). Specifically, Plaintiff alleges that she was terminated due to her refusal to be vaccinated with the COVID-19 vaccine. She was separated from her employment on or about June 1, 2021.

5. No further substantive proceedings have taken place in this action since the receipt of the Summons and Complaint by Defendant.

6. Under 28 U.S.C. § 1446(a), copies of all process and pleadings served upon Defendant, along with a copy of the State Court Docket Sheet, are attached as **Exhibit A**.

II. Removal to This Court is Proper Based on Diversity Jurisdiction

7. This action is removable under 28 U.S.C. § 1441(b) because the United States District Court has original jurisdiction under 28 U.S.C. § 1332(a), which provides that "[t]he district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between – (1) citizens of different states."

8. **The amount in controversy exceeds $75,000.** Plaintiff's Complaint does not claim a specific sum, however, Plaintiff seeks damages and punitive damages. (Ex. A, Complaint Prayer ¶¶ 3-4.) Accordingly, while Defendant denies the validity of Plaintiff's claims as well as Plaintiff's entitlement to the damages she seeks, Defendant acknowledges that, based on the value of the relief sought by Plaintiff in this case, Defendant believes the amount in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000, thus exceeding the jurisdictional amount of $75,000 set forth in 28 U.S.C. § 1332(a).

9. **This action is between citizens of different states.** Plaintiff's Complaint alleges that Plaintiff is an adult individual who resides in West Virginia. (Ex. A, Complaint ¶ 1.)

10. Defendant is not a citizen of the State of West Virginia.[1] It is Delaware LLC, and its principal place of business and corporate headquarters are located in Chicago, Illinois. *See* 28 U.S.C. § 1332(c) ("A corporation shall be deemed to be a citizen of any State by which it has been incorporated and of the State where it has its principal place of business.")

11. Therefore, this Court has original jurisdiction, under 28 U.S.C. § 1332 because the parties are completely diverse, and the amount in controversy exceeds $75,000. Both the complete diversity and the amount in controversy in excess of $75,000 exist as of the date of this Notice of Removal.

12. For the reasons outlined above, Plaintiff's claims are an action over which the District Court of the United States has original jurisdiction pursuant to 28 U.S.C. § 1332, and is therefore properly removable pursuant to 28 U.S.C. § 1441(a) to the District Court of the United States embracing the place where such action is pending.

III. Conclusion

13. Under 28 U.S.C. § 1446(d), a copy of this Notice of Removal, with a Notice of the Filing of the Notice of the Removal, will be sent to counsel for Plaintiff and filed with the Clerk for the Circuit Court of Greenbrier County, West Virginia. A copy of the Notice of Filing of Notice of Removal is attached as **Exhibit B**.

14. By filing this Notice of Removal, Defendant waives no available defenses.

---

[1] Enlivant ES, LLC, a foreign limited liability company, d/b/a Seasons Place Assisted Living Facility is not a properly named Defendant in this matter. Defendant believes that the proper parties are Enlivant AID II ES, LLC and Enlivant Master Management Company, LLC. However, both of these entities are foreign entities as well, as they are Delaware LLCs with a principal place of business in Chicago, Illinois.

WHEREFORE, Defendant respectfully requests that this Court take jurisdiction of this action and issue all necessary orders and process to remove it from the Circuit Court of Greenbrier County, West Virginia to the United States District Court for the Southern District of West Virginia.

Dated: July 9, 2021

Respectfully submitted,

OGLETREE, DEAKINS, NASH,
SMOAK & STEW ART, P.C.

By: /s/*Bethany S. Wagner* _____

Bethany S. Wagner
WV 11341
One PPG Place, Suite 1900
Pittsburgh, Pennsylvania 15222
412-315-6040
bethany.wagner@ogletree.com

Attorney for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of July, 2021, I filed the foregoing via the Court's CM/ECF system and served the foregoing via U.S. First Class Mail, postage pre-paid, to the following:

John H. Bryan, Esq.
411 Main Street
P.O. Box 366
Union, WV 24983

Attorney for Plaintiff

/s/ *Bethany S. Wagner*
Bethany S. Wagner, Esq.
Attorney for Defendant

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IN THE CIRCUIT COURT OF GREENBRIER COUNTY, WEST VIRGINIA

STEPHANIE MCCUTCHEON, Plaintiff, v. ENLIVANT ES, LLC, a foreign limited liability company, d/b/a SEASONS PLACE ASSISTED LIVING FACILITY, Defendant.	)	Civil Action No. CC-13-2021-C-48

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John H. Bryan, Esq.
411 Main Street
P.O. Box 366
Union, WV 24983

Attorney for Plaintiff

/s/ *Bethany S. Wagner*
Bethany S. Wagner, Esq.
Attorney for Defendant

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